REMARKS

Reconsideration and withdrawal of the rejections of record is respectfully requested in view of the amendments and remarks contained herein. Claims 63 to 109 remain pending in this application.

35 U.S.C. § 112

Item 4. The Examiner states that "[c]laims 99-100 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention."

It is respectfully pointed out to the Examiner that claims 99-100 have been amended such that the term "at least about 10" now reads "at least 10." The Examiner is respectfully pointed to the fact that the term specifically held invalid by the court in Amgen, Inc. v. Chugai Pharmaceutical Co. Ltd. (CAFC) 18 USPQ2d 1016 at page 1031 was the term "about." The claims as amended with the term "at least" pass muster with the Amgen court.

35 U.S.C. § 103

Item 5. The Examiner states that "[c]laims 63-67, 69-73, 81-82, 84, 87-90, 101-109 are rejected under 35 USC 103(a) as being unpatentable over Harvey et al. (US Pat. 5,939,259, August 1999) in view of Rudi et al. (WO 98/51693, November 19, 1998). The Examiner further states that "it would have been prima facie obvious, at the time the invention was made to have modified the solid phase lysis and detection method of Harvey to include contacting the solid phase with an RNase." See page 5 of Examiner's Office Action.

The Examiner is respectfully thanked for removing her 102(e) rejection based on Harvey as presented in the Examiner's prior Office Action. However, it is respectfully pointed out to the Examiner that the inclusion of a RNase with the invention taught by Harvey, *i.e.,* an

absorbent material impregnated with guanidine thiocyanate solution having a concentration of 0.5 M to 5.0 M would not have been obvious to one skilled in the art, simply because such an invention would de facto be lacking any utility. The inclusion of a RNase with a denaturing reagent such as guanidinium isothiocyanate as taught by Harvey would have denatured the RNase rendering it non-functional and unable to enzymatically destroy the RNA. It is well known to those skilled in the art that RNase unfolds and/or denatures in the presence of such strong denaturing reagents such as taught by Harvey even at concentrations as low as 0.1 M. The Federal Circuit has produced a number of decisions overturning obviousness rejections due to a lack of suggestion in the prior art of the desirability of combining references. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). Although a prior art device "may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so." 916 F.2d at 682, 16 USPQ2d at 1432.). Upon reviewing the disclosures in Harvey and Rudi, one skilled in the art would have been led to first separate the nucleic acids using a chaotropic reagent, then using a RNase subsequently to remove the RNA, but only after intervening steps to ensure that the RNase is not denatured. Thus, one skilled in the art would not have been motivated to modify Harvey's "absorbent material that has a chaotropic salt impregnated" as stated by the Examiner (See page 4 of the Examiner's Office Action) with a RNase. In contrast, the present invention teaches a unique process optimized to overcome the problems associated with additional steps and RNase degradation. Moreover, the claims have been amended to reflect the aforementioned objective.

Item 6. The Examiner states that "[c]laims 63-67, 71-73, 81-90, 101-109 are rejected under 35 USC 103(a) as being unpatentable over Boom et al (5,234,809) in view of Shieh (US Pat. 6,054,039, April 2000) in view of Rudi et al. (WO 98/51693, November 19, 1998)."

It is respectfully pointed out to the Examiner that claims 63 to 109 as added recite a lysing matrix treated with a lysing reagent and a RNA digesting enzyme. For the prior art to anticipate or render obvious these claims, it must teach every element of the aforementioned claim. Neither Boom nor Shieh teach or suggest such an arrangement. The Examiner is further directed to the discussion in Item 5. above obviating the Rudi reference, thus overcoming the Examiner's obviousness rejection based on the aforementioned references.

Item 7. The Examiner states that "[c]laims 63-67, 71-73, 81-90, 101-109 are rejected under 35 USC 103(a) as being unpatentable over Deggerdal (WO 96/18731) in view of Shieh (US Pat. 6,054,039, April 2000) in view of Rudi et al. (WO 98/51693, November 19, 1998)."

It is respectfully pointed out to the Examiner that claims 63 to 109 as added recite a lysing matrix treated with a lysing reagent and a RNA digesting enzyme. For the prior art to anticipate or render obvious these claims, it must teach every element of the aforementioned claim. Neither Boom nor Shieh teach or suggest such an arrangement. The Examiner is further directed to the discussion in Item 5. above obviating the Rudi reference, thus overcoming the Examiner's obviousness rejection based on the aforementioned references.

Item 8. The Examiner states that "[c]laims 95, 97-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boom (5,234,809) in view of Shieh (US Pat. 6,054,039, April 200) in view of Rudi et al. (WO 98/51693, November 19, 1998) as applied to Claims 63-67, 71-73, 81-90, 101-109 above, and further in view of view of Deggerdal (WO 96/18731)."

It is respectfully pointed out to the Examiner that claims 63 to 109 as added recite a lysing matrix treated with a lysing reagent and a RNA digesting enzyme. For the prior art to anticipate or render obvious these claims, it must teach every element of the aforementioned claim. Boom nor Shieh nor Deggerdal as cited by the Examiner teach or suggest such an

arrangement. The Examiner is further directed to the discussion in Item 5. above obviating the Rudi reference, thus overcoming the Examiner's obviousness rejection based on the aforementioned references.

Item 9. The Examiner states that "[c]laims 68, 99-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boom (5,804,684) in view of Shieh (US Pat. 6,054,039, April 2000) in view of Rudi et al. (WO 98/51693, November 19, 1998) as applied to Claims above 63-67, 69, 71-73, 82-90, 101-109 or Deggerdal (WO 96/18731) in view of Shieh (US Pat. 6,054,039, April 2000) in view of Rudi et al. (WO 98/51693, November 19, 1998) or Harvey et al (US Pat. 5,939,259, August 1999) in view of Rudi et al. (WO 98/51693, November 19, 1998) as applied to Claims 63-67, 69, 71-73, 82-90, 101-109 above and further in view of Su (5,804684).

It is respectfully pointed out to the Examiner that claims 63 to 109 as added recite a lysing matrix treated with a lysing reagent and a RNA digesting enzyme. For the prior art to anticipate or render obvious these claims, it must teach every element of the aforementioned claim. None of the aforementioned prior art cited by the Examiner teach or suggest such an arrangement. The Examiner is further directed to the discussion in Item 5. above obviating the Rudi reference, thus overcoming the Examiner's obviousness rejection based on the aforementioned references.

Item 10. "[C]laims 92-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boom (5,804,684) in view of Shieh (US Pat. 6,054,039, April 2000) in view of Rudi et al. (WO 98/51693, November 19, 1998) as applied to Claims 63-67, 69, 71-73, 82-90, 101-109 above or Deggerdal (WO 96/18731) in view of Shieh (US Pat. 6,054,039, April 2000) in view of Rudi et al. (WO 98/51693, November 19, 1998) as applied to Claims 63-67, 69, 71-73, 82-90, 101-109 or Harvey et al (US Pat. 5,939,259, August 1999) in view of Rudi et al. (WO

98/51693, November 19, 1998) as applied to Claims 63-67, 69, 71-73, 82-90; 101-109 above and further in view above and further in view of Arnold (5,599,667).

It is respectfully pointed out to the Examiner that claims 63 to 109 as added recite a lysing matrix treated with a lysing reagent and a RNA digesting enzyme. For the prior art to anticipate or render obvious these claims, it must teach every element of the aforementioned claim. Shieh, Deggerdal, Arnold, Boom and Harvey as cited by the Examiner do not teach or suggest such an arrangement. The Examiner is further directed to the discussion in Item 5. above obviating the Rudi reference, thus overcoming the Examiner's obviousness rejection based on the aforementioned references.

Item 11. "[C]laims 92-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boom (5,804,684) in view of Shieh (US Pat. 6,054,039, April 2000) in view of Rudi et al. (WO 98/51693, November 19, 1998) as applied to Claims 63-67, 69, 71-73, 82-90, 101-109 above or Deggerdal (WO 96/18731) in view of Shieh (US Pat. 6,054,039, April 2000) in view of Rudi et al. (WO 98/51693, November 19, 1998) as applied to Claims 63-67, 69, 71-73, 82-90, 101-109 or Harvey et al (US Pat. 5,939,259, August 1999) in view of Rudi et al. (WO 98/51693, November 19, 1998) as applied to Claims 63-67, 69, 71-73, 82-90, 101-109 above and further in view above and further in view of Arnold (5,599,667) as applied to claim 92-93 above, and further in view of Hasebe (5,151,345).

It is respectfully pointed out to the Examiner that claims 63 to 109 as added recite a lysing matrix treated with a lysing reagent and a RNA digesting enzyme. For the prior art to anticipate or render obvious these claims, it must teach every element of the aforementioned claim. Shieh, Deggerdal, Arnold, Boom, Harvey or Hasebe as cited by the Examiner do not teach or suggest such an arrangement. The Examiner is further directed to the discussion in Item 5. above obviating the Rudi reference, thus overcoming the Examiner's obviousness rejection based on the aforementioned references.

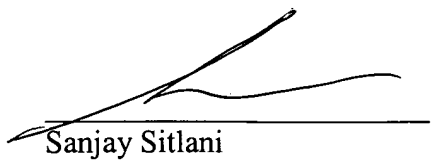
It is respectfully pointed out to the Examiner that claims 63 to 109 as added recite a lysing matrix treated with a lysing reagent and a RNA digesting enzyme. For the prior art to anticipate or render obvious these claims, it must teach every element of the aforementioned claim. None of the aforementioned prior art cited by the Examiner teach or suggest such an arrangement. The Examiner is further directed to the discussion in Item 5. above obviating the Rudi reference, thus overcoming the Examiner's obviousness rejection based on the aforementioned references.

CONCLUSION

Based on the remarks above, applicant believes all pending claims are in condition for allowance.

If the Examiner believes that a conference would be of value in expediting the prosecution of this application, the Examiner is hereby invited to telephone undersigned counsel to arrange for such a conference.

Respectfully submitted,



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